

### **REMARKS**

Claims 2, 4, 5, 16 and 24 are pending. Claims 1, 3, 6-15 and 17-23 have been cancelled. Claim 16 has been amended. Support for the amendment can be found in the originally filed claims and the specification, as explained below. New Claim 24 has been added. Support for the new claim can be found in the specification as explained below. Therefore, no new matter has been added. Favorable consideration of the currently pending claims is respectfully requested in light of the foregoing amendments and following remarks.

#### ***Rejections Under 35 U.S.C. § 102***

In the Office Action, the Examiner rejected Claims 1 and 16 under 35 U.S.C. § 102(b) as being anticipated by Rohr (U.S. Patent No. 5,445,971). Claim 1 has been cancelled, and applicant respectfully submits that the foregoing amendments to Claim 16 and the following remarks overcome the rejection.

Claim 16 has been amended to incorporate the limitations of Claim 3. Applicant submits that Rohr fails to disclose the limitations of Claim 16, and thus does not anticipate amended Claim 16. Applicant therefore respectfully requests that the rejection of Claim 16 under 35 U.S.C. § 102(b) in view of Rohr be withdrawn.

In the Advisory Action, the Examiner indicated that the amendment to Claim 3 introduced new matter “because originally filed claim 3 does not recite a method.” Applicants first note that Claim 3 has been dependent on method Claim 16 since the amendment filed August 8, 2006, and that this amendment did not prompt a new matter rejection. Since this date there have been *two office actions* (November 2, 2006 and June 14, 2007), and in neither of which did the Examiner object to the August 8, 2006 amendment as introducing new matter. Accordingly, the subject matter incorporated into Claim 16 from Claim 3 in the August 14, 2007, amendment has *already been entered* and thus does not

constitute new matter, and applicant submits that the Examiner has improperly refused entry of the amendment.

Notwithstanding that the Examiner has previously allowed entry of an amendment of Claim 3 to depend from a method claim, the Examiner has not provided any support for the refusal to enter the amendment of Claim 16 to incorporate the subject matter of Claim 3. Applicant is not aware of any ***valid grounds*** for refusing entry on the basis that subject matter from an originally filed claim dependent on an apparatus claim cannot be incorporated into a method claim. Even if an amendment can be appropriately refused entry on such grounds, however, applicant submits that it would not be appropriate to do so in this instance, as ***the specification also provides support for the amendment***. For example, the specification describes methods for producing rectangular test strips which have magnetic material on one end (*see, e.g.*, p. 5, lines 13-22). These rectangular strips are further described with reference to their physical dimensions in original Claim 3 and in the specification at p. 8, lines 2-5. The specification also explains that a test strip as so described can be aligned in a magnetic field such that the end of the strip (*i.e.*, “one of the two short edges”) having the magnetically attractive material present thereon will align such that this edge is proximal to the magnet (*see* p. 8, lines 12-20). The “other of the two short edges” ***must*** therefore be farther away from the magnetic field than the “short edge” having the magnetically attractive material thereon. This is further illustrated in Figure 2E and described on p. 13, lines 26-31. Accordingly, applicant submits that Claim 16, as amended, does not introduce new matter, and applicant respectfully requests entry of the amendment.

The Examiner rejected Claims 1-3, 16 and 17 under 35 U.S.C. § 102(e) as anticipated by Hagen *et al.* (U.S. Patent No. 6,872,358) (hereinafter “Hagen”). Applicant respectfully submits that the amendments to the claims overcome the rejection.

As mentioned above, Claim 16 has been amended to incorporate the limitations of Claim 3 and Claim 1 has been cancelled. As discussed in the Amendments

filed April 2, 2007 and August 8, 2006, Hagen discloses a test strip dispenser in which the test strips are “moved” by magnet means. Hagen simply discloses, however, that a magnet is used to dispense test strips, and does not disclose or suggest that exposure of the test strip to a magnetic field causes “a specific spatial alignment or orientation of the test strip” according to amended Claim 16. Moreover, as Claim 16 is a *process* claim, in contrast to cancelled *apparatus* Claim 1, applicant submits that this functional language should be given patentable significance.

Accordingly, Claim 16 is novel and non-obvious over Hagen, and applicant requests that the rejection of Claim 16 under 35 U.S.C. § 102(e) in view of Hagen be withdrawn.

Claim 2 depends directly from amended Claim 16 and contains of all the limitations thereof. For at least the foregoing reasons, applicant respectfully submits that Claim 2 is patentable over Hagen and requests that the rejection of this claim be withdrawn.

### ***Rejections Under 35 U.S.C. § 103***

In the Office Action, the Examiner rejected Claims 4 and 5 under 35 U.S.C. § 103(a) as being obvious over Hagen in view of Hegedus (U.S. Patent No. 3,384,093). Claims 4 and 5 depend from amended Claim 16. Moreover, Hegedus fails to cure the deficiencies of the references discussed above. Accordingly, because amended Claim 16 is believed to be allowable over the prior art of record, Claims 4 and 5 are also believed to be allowable, and applicant respectfully requests that the rejection of these claims under 35 U.S.C. § 103(a) be withdrawn.

In the Office Action, the Examiner rejected Claims 1, 6-8, 16 and 18 under 35 U.S.C. § 103(a) as being obvious over van Rijckevorsel et al. (U.S. Patent No. 4,578,716) (hereinafter “van Rijckevorsel”) in view of Casner (U.S. Patent No. 3,623,603).

As discussed above, Claims 1, 6-8 and 18 have been cancelled, and Claim 16 has been amended to incorporate the limitations of Claim 3. Applicant submits that the combination of van Rijckevorsel and Casner fails to disclose the limitations of Claim 16, as amended. Accordingly, independent Claim 16 is deemed novel and non-obvious over the combination of van Rijckevorsel and Casner, and applicant requests that the rejection of Claim 16 under 35 U.S.C. § 103(a) be withdrawn.

### ***New Claim***

New Claim 24 has been added, incorporating the subject matter on, *e.g.*, pages 10-11 of the specification. Applicant submits that the prior art of record fails to disclose the limitations of Claim 24. In particular, the prior art fails to disclose that an analyte can be applied to “a specific desired location on the test strip, wherein the specific desired location on the test strip is determined by the specific spatial alignment or orientation of the test strip in response to the magnetic field.”

Moreover, Claim 24 is dependent on Claim 16 and incorporates all of its limitations. Accordingly, as applicant submits that Claim 16 is allowable, new Claim 24 is deemed allowable and applicant requests that Claim 24 be given favorable consideration.

In the Advisory Action, the Examiner has indicated that Claim 24 is refused entry because the cited portion of the specification does not provide support for the claimed limitations. Applicant believes that the cited portion of the specification provides the requisite teaching, however, to the extent it does not, applicant submits that ***the claimed subject matter is disclosed elsewhere in the specification.***

The specification supports the claimed limitation of “applying an analyte to a specific desired location on the test strip, wherein the specific desired location on the test strip is determined by the specific spatial alignment or orientation of the test strip in response to the magnetic field.” The specification explains that a magnetic field is applied to orient or

align a test strip with a magnetically attractive material applied thereon, and contacted on the other end of the test strip to ***allow a liquid sample to flow up the test strip from the “other end” and react with the test strip in a specific order***—*i.e.*, from filter pad 50, through conjugate pad 40, then membrane 25 and finally sink pad 30 (p. 8, line 12 to p. 9, line 17). In addition, page 10, lines 1–4 describe the use of test strips for determining the “presence, absence, amount or concentration of one or more specific analyte.” The specification also describes the importance of a liquid sample, *i.e.*, an analyte, contacting substances contained on the test strip ***“in a specific desired order”*** (p. 10, lines 26–28). Finally, p. 10, line 29 through p. 11, line 10 describe a test strip with a magnetic material contained thereon which aligns or orients itself in response to a magnetic field. Applicants thus submit that the foregoing provides sufficient written description support for the subject matter of Claim 24, and applicants respectfully request entry of the claim.

**CONCLUSION**

Based upon the amendments and remarks provided above, applicant believes that Claims 2, 4-5, 16 and 24 are in condition for allowance. A Notice of Allowance is therefore respectfully solicited.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 11-0855.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 815-6500 is respectfully solicited.

Respectfully submitted,

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